7.1 510K Summary of Safety and Effectiveness

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Manufacture: RiverTrail Mobility
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Date Prepared: October 02, 2003
FDA Registration number: None at this time.
Contact Person: Clark Stancil
Proprietary Name of New Device: UB 114
Generic Name of Device: Powered Wheelchair
Classification of the Predicate Device: Class II, ITI
890.3860 Powered Wheelchair
K945936
Jazzy
Proposed regulatory code from 21CFR890.3860: Class II
890.3860 Powered Wheelchair
Panel Code for the Device: 89 Physical Medicine ITI

Intended Use

The intended function and use is to provide mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair.

Description of Device

The Power Wheelchair consists of two basic sections to complete the finished component.

1) The powerbase containing motors, batteries, charger and wheels.
2) The body support system containing contoured adjustable seating and the joystick dual integrated controller.

The UB 114 consists of two motor gearbox combinations that power two 14" diameter front drive wheels. The electrical power source comes from two gel-cell type batteries placed in electrical series for a 24-volt direct current application. Motor control and the battery recharging monitoring is from a Joystick Controller. As part of the electrical system the UB114 employs a battery charger which is mounted "onboard" the power base.

Rear weight, rear balance and rear force load distribution is achieved by two vertical articulating caster wheels. These wheels are mounted directly to the power base. The caster wheels rotate a full 360-degree movement about the vertical mount axis while supporting the rear force load.

Constructed fully from Aluminum Alloy this Power Chair is the first in its class to have a Uni-Body style frame. All key electrical components, batteries, motor gearboxes, battery charger and wiring are enclosed within the Uni-body frame. The exterior is finished in a high performance and durable epoxy type paint.

Technological Characteristics/Comparison Summary

The UB114 is substantially equivalent to the predicate device in as they are both Joystick controlled. Utilize onboard battery charger and batteries. They are both mid-wheel drive power chairs with rear casters and front anti-tip wheels.

Non-Clinical tests performed for determination of Substantial Equivalence

Tests listed in the Guidance Document for the Preparation of Premarket Notification 510K Applications for Mechanical and Powered Wheelchairs and Motorized Three Wheeled Vehicles.

ANSI/RESNA WC/02 1991 Wheelchair Standard for Static Stability
ANSI/RESNA WC/02 1991 Wheelchair Standard for Dynamic Stability
ANSI/RESNA WC/Vol. 2-1998 Wheelchair Standard for EMC Testing

Conclusions of Non-Clinical Tests

The UB114 has the same intended use and similar technological characteristics as the Predicate Device. The non-clinical testing and predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

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The UB114 also employs a set of front stabilizer wheels that are placed to the front centerline of the drive wheels. The stabilizer wheels aid the user if they encounter a situation that may create an unsafe situation and help keep the Powered Wheelchair from tipping forwards or to the front left or front right sides.

The front stabilizer wheels and support arms also aid in the protection for the user's feet and legs.

All electrical components (motor gearbox combinations, batteries, battery charger, and internal wring) are housed/enclosed within a **solid aluminum alloy Uni-body frame.**

The body support system contains contoured adjustable seating with a full 180-degree tilt back for the user. A puff-bladder style or cam-lock style lumbar support is standard for all seating in the UB114.

The joystick controller attached to the seating system with a combination length adjustment and tilt angle plate system. This allows the user to totally custom fit the angle and length of position for the joystick.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2003

Rivertrail Mobility
c/o Entela, Inc.
N. E. Devine
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K033827
Trade/Device Name: UB 114
Regulation Number: 890.3860
Regulation Name: Wheelchair, powered
Regulatory Class: II
Product Codes: ITI
Dated: December 10, 2003
Received: December 10, 2003

Dear: Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

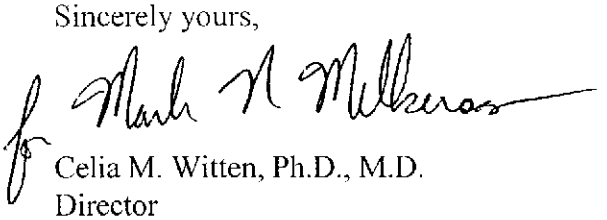
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7.2 Indication for Use

510k Number (if known) _____

Device Name: UB114

Indications For Use: The intended function and use is to provide mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** __X_____
(Part 21 CFR 801 SubPart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033827